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Paper 10
Entered: October 14, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners.

Case IPR2014-00549
Patent 6,316,023 B1

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and SCOTT E. KAMHOLZ, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Noven Pharmaceuticals, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1, 2, 4, 5, 7, and 8 of U.S. Patent No. 6,316,023 B1 (Ex. 1001, "the '023 patent"). Paper 1 ("Pet."). Novartis AG and LTS Lohmann Therapie-Systeme AG (collectively, "Patent Owner"), filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon considering the Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1, 2, 4, 5, 7, and 8 of the '023 patent. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

According to Petitioner and Patent Owner, the '023 patent is involved in various district court actions, including two actions involving the parties to this proceeding, titled: *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, 1:13-cv-00527 (D. Del.); and *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, 1:14-cv-00111 (D. Del.). Pet. 1–2; Paper 6 at 2.

Additionally, Petitioner has filed a petition for *inter partes* review of related U.S. Patent No. 6,335,031. IPR2014-00550, Paper 1.

B. The '023 Patent (Ex. 1001)

The '023 patent is directed to a pharmaceutical composition comprising (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl carbamate ("compound A"; "rivastigmine"; "S-enantiomer of RA_7") in the form of a free base or acid addition salt, along with an antioxidant, and a diluent or carrier. Ex. 1001, 1:7–47. "Compound A is useful in inhibiting acetylcholinesterase in the central nervous system, e.g. for the treatment of Alzheimer's disease." *Id*. at 1:15–17. A transdermal composition comprising compound A in the form of a free base or acid addition salt, two polymers, and a plasticizer is disclosed in the prior art. *Id*. at 1:18–22. The inventors of the '023 patent explained that the composition of the prior art "is susceptible to degradation, particularly in the presence of oxygen." *Id*. at 1:23–25. The '023 patent states:

> The present applicant has found that stable pharmaceutical compositions comprising compound A can now be obtained, which show insignificant degradation of compound A over a prolonged time period, e.g. 2 years, as indicated by standard tests, e.g. stress tests.
>
> In one aspect, the invention provides a pharmaceutical composition comprising Compound A in free base or acid addition salt form and an anti-oxidant.
>
> The pharmaceutical compositions of the present invention show a reduction in degradation by-products in stress stability tests.

Id. at 1:30–39.

C. Illustrative Claims

Independent claims 1 and 7 of the '023 patent are illustrative of the claims at issue:

> 1. A pharmaceutical composition comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition.

Ex. 1001, 8:17–20.

> 7. A transdermal device comprising a pharmaceutical composition comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition.

Id. at 8:44–50.

D. The Prior Art

Petitioner relies on the following prior art:

Enz	UK Patent Application GB 2,203,040 A, published Oct. 12, 1988 ("Enz")	Ex. 1002
Handbook	Handbook of Pharmaceutical Excipients (A. Wade & P.J. Weller eds., 2d ed. 1994) ("the Handbook")	Ex. 1003
Sasaki	JP Patent Application 59-184121, published Oct. 19, 1984 ("Sasaki")	Ex. 1005
Ebert	WO 95/24172, published Sept. 14, 1995 ("Ebert")	Ex. 1006

Kissel	EP Patent Application 0155229A2, published Sept. 18, 1985 ("Kissel")	Ex. 1007
Rosin	US 4,948,807, issued Aug. 14, 1990 ("Rosin")	Ex. 1008
Elmalem	*Antagonism of Morphine-Induced Respiratory Depression by Novel Anticholinesterase Agents*, 30 NEUROPHARMACOLOGY. 1059-1064 (1991) ("Elmalem")	Ex. 1009

Petitioner also relies on declarations of Dr. Agis Kydonieus (Ex. 1010) and Dr. Christian Schöneich (Ex. 1011).

E. The Asserted Grounds

Petitioner challenges claims 1, 2, 4, 5, 7, and 8 of the '023 patent on the following grounds:

Reference(s)	Basis	Claims
Enz and the Handbook, optionally in view of Rosin and/or Elmalem and/or Ebert	§ 103(a)	1, 7
Enz and the Handbook, and/or Rosin, and/or Ebert	§ 103(a)	2
Enz and the Handbook and/or Ebert	§ 103(a)	4, 5
Enz, the Handbook, and Ebert or Kissel	§ 103(a)	8
Enz and Sasaki	§ 103(a)	1, 2, 4, 5, and 7
Enz, Sasaki, and Ebert or Kissel	§ 103(a)	8

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